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February 27, 2006

VIA HAND DELIVERY AND CM/ECF

The Honorable Kent A. Jordan
J. Caleb Boggs Federal Building
844 N. King Street
Room 6325
Lockbox 10
Wilmington, DE 19801

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,
C.A. No. 05-586-KAJ

Dear Judge Jordan:

We write on behalf of Andrx in opposition to Biovail's February 24, 2006 letter requesting that the Court compel Andrx to supplement its responses to Biovail Interrogatory Nos. 1 and 2, and to produce documents regarding the proposed sale, and development of Andrx's product.[1]

I. Biovail's Request is Premature

Biovail has failed to engage in a good faith meet and confer regarding its discovery complaint. In its February 17, 2006 letter responding to Biovail's discovery complaints, Andrx offered to meet and confer regarding Biovail's discovery complaints. (Ex. 1). *Biovail never responded to this offer*. Further, Biovail did not respond to the February 17, 2006 letter regarding its discovery complaint until *after* filing its February 24, 2006 letter with the Court.[2] Indeed, several of the issues that Biovail included in its requests were not previously discussed as part of the meet and confer because Biovail failed to identify those issues as being in dispute. Accordingly, Biovail's request should be denied as being premature.

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[1] Andrx requested the February 28, 2006 discovery conference to discuss *its* complaints regarding Biovail's ongoing discovery abuses and to address issues that the Court did not have time to address during the January 26, 2006 discovery conference. Although we are prepared to address Biovail's issues, before receiving Biovail's February 24 letter, we were not aware that Biovail intended to forego its meet and confer obligation and raise the issues with the Court.

[2] Biovail provided a partial response to Andrx's February 17th letter at approximately 7:50 p.m on February 24, 2006. (Ex. 2).

II. Andrx's Responses to Interrogatory Nos. 1 and 2 are Not Deficient for this Stage of the Case

First, as a result of Biovail's refusal to engage in a good faith meet and confer, it is unclear whether Andrx's responses related to its non-infringement contention (*i.e.* Interrogatory No. 1) is at issue and if so, how its responses are deficient. Biovail first identified Interrogatory No. 1 in its discovery complaints to Andrx in its February 13, 2006 letter. (Ex. 3). Biovail's February 13, 2006 letter, however, only identified alleged deficiencies concerning Andrx's invalidity contentions and did not identify any alleged deficiencies concerning Andrx's non-infringement contentions. Accordingly, Andrx sought clarification from Biovail that its complaints are not directed towards Andrx's responses with respect to its non-infringement contentions. (Ex. 1) Biovail *never* responded to Andrx's request.

Further, Biovail's February 24, 2006 letter does not present any argument concerning how Andrx's non-infringement contention is deficient. Indeed, Biovail's entire argument concerning Andrx's responses to interrogatories is directed to Andrx's invalidity contention, which is the subject matter of Interrogatory No. 2. Accordingly, Biovail has failed to meet its burden for establishing that Andrx's response to Interrogatory No. 1 is deficient and this request should be denied.

Second, with respect to Andrx's response to Interrogatory No. 2 concerning its invalidity contention, this Court has already reviewed Andrx's response and determined that it was sufficient *for this stage of the case*. As the Court stated:

> So I've taken a look at what their answer was. It's certainly not going to be enough to pass muster at trial. I'll warrant you that. *But we're not at trial. We're at the point now where each side is discovering what the other side's position is and, they've told you enough for you to say at this juncture*, okay, I'm going to have to answer their interrogatories about secondary considerations.

(Transcript p. 12, ll. 5 – 11) (emphasis supplied).

Further, as the Court previously recognized, Andrx's invalidity contention is contingent on how Biovail interprets the claims of the '791 patent. (*Id.*, p.8, ll. 16 – p.9, ll. 9). This contingency is important because this is the *second* case between the two parties involving the *same* patent. In the first case, *Biovail Corp. Int'l. v. Andrx Pharms. Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000), *aff'd,* 239 F.3d 1297 (Fed. Cir. 2001), based on the claim construction of the '791 patent, Andrx's proposed product was found *not* to infringe. The proposed product in this case is virtually identical in all relevant respects to the product found not to infringe, and thus should also be found not to infringe. Thus, Andrx believes that Biovail will seek a different claim construction that is broader than the claim construction from the first case. Biovail, however, refused to answer Andrx's interrogatories seeking this information. Thus, Andrx does not know how Biovail is interpreting the claims to cover its proposed product. Nevertheless, Andrx answered Interrogatory No. 2 based on information then available to it, which the Court has already found was sufficient at this juncture. Andrx has informed Biovail, "[a]lthough

Andrx's responses are sufficient for this stage of the case, Andrx will continue to comply with the Court's instructions and the Fed. R. Civ. P. 26(e) and supplement its discovery responses, at the appropriate time as additional information becomes available." (Ex. 1). Accordingly, Biovail's request that Andrx supplement its response to Interrogatory No. 2 is moot because Andrx already agreed to do so as additional information becomes available.

III. ANDRX'S PRODUCTION OF DOCUMENTS

Documents regarding (1) Andrx's projected sales and projected market share of its proposed product; and, (2) purchase orders and receipts for the raw materials used in various experiments are not relevant to any issues in this action and not reasonably calculated to lead to the discovery of admissible evidence. Further, searching for and producing all purchase orders and receipts for raw materials used in experiments would be unduly burdensome.

Biovail alleges that the Andrx's sales projections and projected market share concerning its proposed product is relevant to "commercial success." Andrx, however, has not made any sales of its proposed product and projections concerning Andrx's sales of its proposed product is not relevant to "commercial success." Nevertheless, Andrx has made a reasonable and diligent search for sales and marketing documents and has produced all responsive, non-privileged documents it was able to locate after such search. Further, in light of Biovail's discovery complaints, Andrx is conducting a *second* search and will produce responsive, non-privileged documents, if any, that are located after this *second* search. Thus, this issue is moot.

Biovail makes no attempt to explain how purchase orders for raw materials used in research and *not the accused product* has any relevance to the subject matter of this action. The focus of an infringement inquiry under 35 U.S.C. 271(e)(2)(A) is "on what is likely to be sold following FDA approval" of the defendant's proposed product. *Glaxo, Inc v Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). This hypothetical final product analysis "is properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Id.*, at 1569. Andrx has already produced its ANDA including technical documentation regarding its raw materials (Section VIII of the ANDA). In contrast, documents regarding the purchase orders and receipts for raw materials used in various experiments that are not the subject matter of Andrx's ANDA is not relevant to the infringement analysis. Accordingly, Biovail is not entitled to these documents.

Furthermore, it would be unduly burdensome for Andrx to search for and produce all purchase orders and receipts for all raw materials used in experiments identified in Andrx's laboratory notebooks. Should this Court determine that the raw materials used in experiments that are not the subject matter of Andrx's ANDA is relevant to this action, Andrx may be able to provide the requested information in a manner that is far less burdensome than producing purchase orders and receipts. For example, the raw materials identified in the notebooks are also referred to by an Andrx code number (as well as the receiving number). If Biovail identifies which Andrx code number they would like additional information for, Andrx may be able to more easily search for and provide such information. Andrx believes that this is a reasonable compromise that will provide Biovail with the discovery it requests without unduly burdening Andrx.

Respectfully submitted,

/s/ Richard L. Horwitz

Richard L. Horwitz

RLH:nmt/721436
cc: Clerk of Court (via electronic filing)
Jack B. Blumenfeld (via electronic filing and email)
Joseph M. O'Malley, Jr. (via email)
Dominick A. Conde (via email)
Anthony Son (via email)

EXHIBIT 1

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CLIENT/MATTER NUMBER
054657-0103

February 17, 2006

VIA FACSIMILE

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Re: Biovail v. Andrx Pharmaceuticals LLC et al.,
Civil Action No. 1:05-cv-586

Dear Mr. Ratliff:

We write in response to your February 13, 2006 letter to Steve Maddox regarding Andrx's interrogatory responses and document production. Your mischaracterization of Andrx's statements and positions is unnecessary and unproductive. *First*, your statement that "Andrx's assertion that on the eve of the January 26, 2006 discovery conference, Biovail 'ginned up' discovery complaints in an attempt to deflect attention from an alleged refusal to produce discovery to Andrx is nonsensical as Biovail never even raised its discovery complaints with the Court" is false and inconsistent with the transcript from the January 26, 2006 conference. For example, the Court stated:

> THE COURT: Okay. Now help me out with the timing here, too, because your opponent [Andrx] makes the assertion that this is a ginned-up position for you to take in this call. That in the months since they propounded this answer you didn't say boo about it being a problem until the prospect of dealing with the Court on this call came up and then that is when you decided: Well, wait a second, their answer is inadequate and therefore we don't have to answer. I want to give you a chance to go ahead and answer that.

(Transcript of Jan. 26, 2006 hearing ("Transcript"), p. 9, ln. 22 – p. 10, ln. 5).

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In responding to the Court's inquiry, Mr. O'Malley raised its discovery complaints and argued why it believes Andrx's responses are deficient. (Transcript, p. 10, ln. 6 – p. 11, ln. 11. Notably absent from Mr. O'Malley's response is any indication that Biovail was not at that time raising its discovery complaints with the Court. We request that you refrain from making such false accusations in the future.

Second, your allegation that "Andrx ignored Biovail's proposal to exchange supplemental interrogatory responses" is also false. We responded to Biovail's proposal in our February 2, 2006 letter when we informed you that Biovail does not have the right to "dictate conditions upon which it will produce discovery, nor does it have the right to dictate the conditions upon which it will obey the Court's instructions." Interestingly, although Biovail indicated that it was prepared to provide supplemental responses by Monday February 13, 2006 (*see* February 1, 2006 letter from Preston Ratliff), we have not received Biovail's supplemental responses. It appears that although Biovail was ready to provide Andrx with supplemental responses interrogatories on February 13, 2006, it intends to hold those responses hostage until it can extract concessions from Andrx that it is not entitled to receive.

Biovail's continuing refusal to provide its supplemental responses to interrogatories is a direct violation of the Court's instructions and contrary to law. Indeed, as the Court stated:

> But what the law doesn't provide is for you [Biovail] to turn to essentially self-help by saying, you know what, we really don't like your answer so we're not giving you anything that you are asking for in this regard until we like your answer more.

(Transcript p. 11, ln. 21-25).

Further, it is well established that Biovail's conditions upon which it will produce discovery is directly inconsistent with the Federal Rules of Civil Procedure and, thus, has been consistently rejected by courts as utterly baseless and improper. *See* Fed. R. Civ. P. 26(d); *Convolve, Inc. v. Compaq Computer Corp.*, 00 Civ. 5141 (JSM), 2000 WL 1480363, at *1 (S.D.N.Y. Oct. 6, 2000) ("As Rule 26(d), Fed. R. Civ. P. states, 'methods of discovery may be used in any sequence, and the fact that a party is conducting discovery, whether by deposition or otherwise, shall not operate to delay any other party's discovery.' Under the Federal Rules' liberal discovery regime, without judicial intervention *a party can neither assert priority in discovery nor make its responses to another party's discovery requests contingent upon reciprocal compliance.*" (citing *Burda Media, Inc. v. Blumenberg*, 97 Civ. 7167, 1999 WL 413469, at *5 (S.D.N.Y. June 21, 1999)) (emphasis supplied).

In light of the well-established law on this issue, Biovail's violation of the Court's instructions, and continuing refusal to provide discovery despite the fact that Biovail was prepared to exchange supplemental responses by February 13, 2006, Andrx reserves the right to seek all appropriate relief from the Court, including sanctions for Biovail's discovery misconduct.

With respect to the other issues raised in your letter, we address each item in the order in which they were presented:

I. Andrx's Interrogatory Responses

We understand your reference to Interrogatory No. 1 in your February 13, 2006 letter is based only on the fact that Andrx's response to Interrogatory No. 2 incorporated by reference the invalidity portions in its response to Interrogatory No. 1. Please let us know immediately if our understanding is incorrect because Biovail has not previously raised any complaints regarding Andrx's response to Interrogatory No. 1 with respect to its non-infringement contentions.

Your citation to "hornbook patent law" as the "authority" supporting the level of detail that Biovail seeks and listing what it believes are the elements for the anticipation and obviousness defenses ignores our simple request for Biovail to provide authority for the level of detail you seek *at this stage in the case*. Indeed, as we previously indicated to you, the Court already reviewed our response to Interrogatory No. 2 and determined that it was sufficient *for this stage of the case*. (Transcript p. 12, ln. 5 – 11). Although Andrx's responses are sufficient for this stage of the case, Andrx will continue to comply with the Court's instructions and the Fed. R. Civ. P. 26(e) and supplement its discovery responses, at the appropriate time as additional information becomes available.

Subject to Andrx's objections, it is our understanding that there are no "opinion, study, analysis, report, test, or investigation requested, obtained, and/or conducted by Andrx relating to the infringement or validity of the '791 patent" other than those prepared by counsel, which we have already identified. The opinion of counsel obtained by Andrx relating to the patent-in-suit is obviously privileged and Andrx has not waived the privilege. We note that you have not explained how any of the information Biovail seeks related to the opinion of counsel is relevant to any of the issues in this action in light of the fact that willful infringement is not an issue in this action.

II. Andrx's Document Production

Andrx has made a reasonably diligent search for responsive documents and, subject to its objections, has already produce all relevant, non-privileged documents responsive to Biovail's requests. Indeed, we note that Andrx has produced over 5 times more pages of documents than Biovail. Nevertheless, we will make another search for (1) reports regarding the development of the formulation of its proposed tableted products, (2) batch records for extended-release pellet lots 700B001A, 1338-78, 151R005, 151D025, and 151D061, (3) manufacturing records for the 420 mg. tablet lots 695R020, 695P021 and for the samples provided on December 30, 2005, and Andrx will produce all relevant, non-privileged documents, if any, to the extent not already produced.

We agree that both parties shall produce supplemental FDA correspondence (Biovail's NDA No. 21-392 and Andrx's ANDA No. 77-686) every two months.

Andrx has agreed to provide Biovail with all FDA correspondence concerning its ANDA No. 77-686. Indeed, Andrx has already produced those documents to Biovail and will continue to do so pursuant to the parties' agreement to periodically produce supplement FDA correspondence. While the FDA documents concerning Andrx's ANDA No. 77-686 may be relevant to the subject matter of this action, the FDA Form 483 letter concerning manufacturing facilities of Andrx's existing, approved products, is not. Indeed, it is undisputed that Andrx's approved products are not at issue in this litigation. Further, the fact that the "beads" employed in Andrx's proposed unapproved product may be identical in composition to beads in other products not at issue in this litigation does not render all documents related to the approved product not at issue in this action relevant to this litigation. Nevertheless, should the FDA require Andrx to change its manufacturing procedures for its proposed unapproved product, we anticipate that those changes would be reflected in the correspondence with the FDA related to ANDA No. 77-686, which we already stated will be produced.

The only product at issue is the proposed product that is the subject of Andrx's ANDA. The technical documentation concerning that product, including the raw materials, are in the ANDA. Accordingly, Andrx already produced the technical documentation, including the raw materials, related to the sole product at issue. (*See, e.g.*, Section VIII of the ANDA). To the extent that Biovail is seeking technical documentation for products that are not the subject matter of the ANDA, we fail to see the relevance of such technical documentation to the issues in this action.

There has been no failure by Andrx to produce documents regarding its notice letters, organizational charts or document retention, disposal or destruction policies. To the best of our knowledge, after a reasonably diligent search, there are no responsive, non-privileged documents regarding these categories in Andrx's possession, custody or control. Our investigation and discovery is continuing and should we locate any responsive, non-privileged documents, if any, they will be provided.

Although you accuse Andrx for failing to address each of the missing documents identified in Biovail's January 24, 2006 letter, you do not identify any documents that Andrx failed to address. Instead, you improperly shift the burden of identifying documents that Andrx allegedly failed to address to Andrx. We are not clairvoyant and thus cannot determine what you think is missing from our February 3, 2006 letter. Further, it is not our burden to compare the two letters and determine what discovery complaints you think Andrx "failed" to address. If you truly believe that we have not addressed all of the issues raised in your January 24, 2006 letter, identify those issues for us and we will respond, as appropriate.

Finally, your threat that Andrx either provide the requested discovery or Biovail will raise "Andrx's discovery failures" with the Court is an ultimatum and not a good faith effort to meet and confer. Although it does not appear that Biovail is genuinely interested in engaging in a good faith meet and confer to resolve its discovery complaints, we are nevertheless available for a meet and confer. Let me know if Biovail would like to meet and confer or if this is another ploy to deflect attention from its discovery misconduct and refusal to produce discovery.

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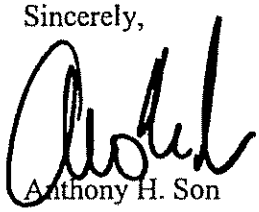
Concerning your statement that Biovail will raise Andrx's discovery failures with the Court during the February 28, 2006 conference, has Biovail already contacted the Court and scheduled a conference on its discovery complaints for that date? If not, we object to Biovail's attempt to use the time Andrx reserved with the Court to raise its own discovery complaints. As you know, the Court's time is very limited and we refuse to be prejudiced by Biovail's continuous attempts to delay resolution of its discovery misconduct and the issues that the Court did not have the time to address during the January 26, 2006 conference. If a discovery conference becomes necessary to address Biovail's discovery complaints against Andrx, it can request its own dates from the Court.

Sincerely,



Anthony H. Son

cc: Jack Blumenfeld
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February 13, 2006

VIA FACSIMILE

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Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,
Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This concerns Andrx's February 2, 2006 letter, and its February 3, 2006 letter in response to Biovail's January 24, 2006 and February 1, 2006 letters regarding Andrx's interrogatory responses, and Andrx's document production.

As initial matter, Andrx's assertion that on the eve of the January 26, 2006 discovery conference, Biovail "ginned up" discovery complaints in an attempt to deflect attention from an alleged refusal to produce discovery to Andrx is nonsensical as Biovail never even raised its discovery complaints with the Court. Further, it is disappointing that Andrx ignored Biovail's proposal to exchange supplemental interrogatory responses. During the discovery conference, the Court directed the parties to "give responsive discovery to the properly propounded contention interrogatories . . . ." (Tr. 13.)

I. Andrx's Interrogatory Responses

Regarding Andrx's interrogatory responses, Andrx's responses to Interrogatory Nos. 1 and 2 are insufficient. In its February 3, 2006 letter, Andrx complained that Biovail has not provided any authority for the "level of detail" it seeks in response to Interrogatories Nos. 1 and 2. The authority, of course, is the respective standards for anticipation and obviousness. It is hornbook patent law that a defense of anticipation requires a showing that all elements of an invention are set forth in a single prior art reference, and that a defense of obviousness requires a showing of: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claims and the prior art; and (4) why the differences between the

claims and the prior art would have been obvious. Further, Andrx's suggestion that the Court indicated that its responses to Biovail Interrogatory Nos. 1 and 2 were sufficient are undercut by the fact that the Court stated that Andrx "better start being forthcoming." (Tr. 12.)

As to Andrx's response to Interrogatory No. 3, this interrogatory is not directed solely to opinions prepared by counsel. It is directed to any opinion, study, analysis, report, test, or investigation requested, obtained, and/or conducted by Andrx relating to the infringement or validity of the '791 patent. With regard to the written opinion that Andrx received from Martin Endres, Biovail does not seek the substance of this opinion, but rather other information, e.g., whether the opinion relates to infringement or validity, the date authored, and the names of the persons who received copies of the opinion. (*See* Biovail Interrogatory No. 3, paragraphs (a) through (i).) Further, the fact that Andrx will identify this opinion on a privilege log on some unspecified date in the future, does not relieve Andrx from providing now a full and complete answer to Biovail's interrogatory.

II. Andrx's Document Production

Andrx's assertion that it has produced all "meeting minutes, notes, tests, development and analyses in Andrx's development of its product" cannot be correct. Plainly, additional documents exist, but have not been produced. For example, Andrx failed to produce any reports (summary or otherwise) regarding the development of the formulation of its proposed tableted products. Andrx also failed to produce batch records for extended-release pellet lots 700B001A, 1338-78, 151R005, 151D025, and 151D061. (*See* ANDCLA 102027-102130.) Further, Andrx manufactured 420 mg tablet lots 695R020 and 695P021. Andrx, however, failed to produce manufacturing records from start to finish for those tablets. In addition, Andrx failed to produce the manufacturing records for the samples of active pellets, and extended-release pellets that it produced on December 30, 2005.

As to FDA correspondence, Andrx incorrectly stated that Biovail complained that Andrx has not supplemented its December 30, 2005 and January 6, 2006 production with subsequent FDA correspondence. On this basis, Andrx proposed that the parties periodically exchange supplemental FDA correspondence. Biovail is agreeable to an exchange every two months supplementing FDA correspondence for its NDA No. 21-392, and Andrx's ANDA No. 77-686.

Andrx's assertion that the May 2005 Form 483 letter is not relevant because it "concerns manufacturing facilities of Andrx's existing, approved products" is inconsistent with its position in the litigation. In particular, Andrx has said that "[t]he beads employed in the Andrx Proposed Product are identical to the composition of the beads employed in its TAZTIA® product." (*See* Andrx's June 22, 2005, and August 30, 2005 Notice Letters, p. 7.) To the extent Andrx is forced by the FDA to change its manufacturing procedures that is plainly relevant to this litigation, and so is the May 2005 Form 483 letter. Andrx's assertion is also inconsistent with the fact that the FDA has placed approval of ANDA No. 77-686 on hold as a result of that

Form 483 letter. Biovail is entitled to any correspondence that has (or may have) an effect on the manufacture, and approval of Andrx's proposed tableted products.

As to Andrx's failure to produce purchase orders and receipts for its raw materials, such documents are plainly relevant to this case. (*See* Biovail document request nos. 58-60.) For example, Andrx's laboratory notebook no. SR3657, which relates to the development of Andrx's proposed products, includes many experiments employing the use of colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, and polyethylene oxide. (*See* ANDCLA 102027-102130.) The laboratory notebook identifies each material by reference to an Andrx internal receiving number. It, however, does not include any information identifying the manufacturer, and in many instances, the specific grade of material used. Without this information it is impossible to determine what was used in the experiments, and how Andrx developed its proposed tableted products. Further, laboratory notebook no. SR3657 includes experiments employing the use of other materials tried by Andrx, e.g., pregelatinized starch, Eudragit S100, lactose monohydrate spray dried, confectionary sugar, and glycerol monostearate. These materials are also identified only be reference to an Andrx internal receiving number. Documentation of Andrx's purchases and receipts are relevant because they would allow Biovail to determine the manufacturer and specific grade of ingredient used by Andrx during the development of its proposed tableted products.

As to Andrx's failure to produce documents regarding its notice letters, such documents are not necessarily work product or subject to the attorney-client privilege. For example, documents authored by non-attorney employees that simply discuss the substance, or content of Andrx's notice letters do not constitute attorney work product, and are not privileged.

As to Andrx's failure to produce organizational charts, Biovail's document request No. 64 is not limited to "current" organizational charts of Andrx. Biovail is entitled to any organizational chart of Andrx since the time it commenced development of its proposed tableted products.

As to Andrx's failure to produce document retention, disposal, or destruction policies, Andrx contends that it does not have a written corporate document retention policy. Please confirm that Andrx has never had any document retention, disposal, or destruction policy (written or otherwise) since the time it commenced development of its proposed tableted products.

Finally, Andrx's February 3, 2006 letter fails to address each of the missing documents identified in Biovail's January 24, 2006 letter. Please review Biovail's January 24, 2006 letter and attachment Tab A again.

If Andrx does not promptly agree to supplement its interrogatory responses, and produce all requested documents, Biovail will have no choice but to raise Andrx's discovery failures with the Court during the February 28, 2006 conference.

Very truly yours,

Preston K. Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq.
William J. Cattie, III, Esq.
Martin P. Endres, Esq.
Herschel Sparks, Esq.

EXHIBIT 3

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February 24, 2006

VIA FACSIMILE

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Washington, DC 20007-5143

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,
Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Son:

This concerns Andrx's February 17, 2006 letter in response to Biovail's February 13, 2006 letter regarding Andrx's interrogatory responses, and Andrx's document production.

Andrx's letter did not address meeting minutes, and notes regarding the development of its proposed tableted products. While Andrx produced some such documents (*see, e.g.*, ANDCLA 102333), Biovail has not located such documents that are contemporaneous with the development of Andrx's proposed tableted products. Please confirm that Andrx will search for and produce those documents. In addition, Andrx's letter did not address documents reflecting how it selected the particular ingredients in its proposed tableted products, including documents reflecting why its proposed tableted products include colloidal silicon dioxide in lieu of the confectionary sugar included in Andrx's 420 mg tablet lots 695020 and 695P021. Again, please confirm that Andrx will search for and produce those documents.

As to Andrx's May 2005 Form 483 letter, based on representations in its February 17, 2006 letter that Andrx's approved products are irrelevant to any issue in this litigation, and that the only products at issue in this litigation are the proposed products of ANDA No. 77-686, Biovail will forgo discovery of the May 2005 Form 483 letter and related documents at this time. Biovail preserves the right to pursue such discovery in the future.

Based on Andrx's letter, Biovail understands that Andrx will search for and produce: (1) reports regarding the development of its proposed tableted products; (2) manufacturing records for extended-release pellet lots 700B001A, 1338-78, 151R005, 151D025, and 151D061; (3) manufacturing records for 420 mg tablet lots 695R020 and 695P021; and (4) manufacturing records for the samples of active pellets, and extended-release pellets that Andrx produced on December 30, 2005.

Biovail also understands that Andrx will continue to search for and produce documents regarding the substance or content of its notice letters, company organizational charts, and company document retention, disposal, and destruction policies, and that Andrx agreed to supplement its FDA correspondence for ANDA No. 77-686 every two months.

Very truly yours,

Preston K. Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq.
Richard L. Horwitz, Esq.
Martin P. Endres, Esq.
Herschel Sparks, Esq.